PRACTICAL AND ETHICAL PROBLEMS WITH 'VULNERABILITY'

by

Jennifer L. Damelio

B.A., Ursinus College, 2006

Submitted to the Graduate Faculty of

the School of Arts and Sciences in partial fulfillment

of the requirements for the degree of

Master of Arts in Bioethics

University of Pittsburgh

2011

UNIVERSITY OF PITTSBURGH

Center for Bioethics and Health Law

This thesis was presented

by

Jennifer L. Damelio

It was defended on

April 19, 2011

and approved by

Alan Meisel, JD, Professor of Law, Professor of Bioethics, School of Law, Center for Bioethics and Health Law, University of Pittsburgh

David Barnard, PhD, JD, Professor of Medicine, Affiliated Faculty of Law, Affiliated Faculty Center for Global Health, University of Pittsburgh

Thesis Director: Lisa S. Parker, PhD, Associate Professor, Center for Bioethics and Health Law, University of Pittsburgh

PRACTICAL AND ETHICAL PROBLEMS WITH 'VULNERABILITY'

Jennifer L. Damelio, M.A.

University of Pittsburgh, 2011

This project analyzes the concept of vulnerability and the way that it is applied as a label in the context of human subject research. Vulnerability as a concept represents concern for an individual's or group's acute inability to protect her or their own interests. In the research context, this concept is applied as a label across large populations in an attempt to signify a need for added protections when these populations are enrolled in research because of the heightened susceptibility of these groups to harms, wrongs, or exploitation. Although there are legitimate reasons for extending heightened protections to particular individuals, the way the concept is currently applied in the research context fails to protect all those who are in need of protections, and furthermore, causes harm or wrongs individuals and those populations so-termed 'vulnerable'. The label is too broad, and tends to extend protections to those who are not in need of them to their potential detriment. Furthermore, the label fails to draw attention to the manner in which these groups are vulnerable and thus appropriate and adequate protections may not be offered. The label of 'vulnerability' can also carry with it a stigma, which may be internalized by members of these vulnerable populations. Instead of conceptualizing vulnerability as an individual's or group's inability to protect her or their own interests due to some feature of those so labeled, vulnerability should be conceptualized in a way that does not obscure the relational features of the concept – i.e., that the type of vulnerability of interest in research frequently is the result of relationships of power, and research protections should adopt a framework based on such a conceptualization. The focus ought to be on those features or situational characteristics

that are likely to override an individual's assertion of her own interests. This approach would avoid the situating of the inability to protect one's own interests within the individual, and would allow for a practical enactment of protections which serve everyone equally when they are in situations of experiencing vulnerability in relation to a particular other or institution.

TABLE OF CONTENTS

1.0 INTRODUCTION

Vulnerability is a concept that denotes a concern for an individual's inability to protect her own interests. Generally, in everyday language, vulnerability is a weakness. It indicates a heightened susceptibility to being harmed or wronged. The concept of vulnerability is frequently employed in human subject research. Populations which are particularly prone to being harmed or wronged for a number of varying reasons are named as vulnerable in research guidelines and in other literature surrounding the protection of human research subjects. These populations are identified so that special protections can be put into place regarding their enrollment and participation in research. These special protections can take varying forms, and they are directed at compensating for the particular susceptibility of these vulnerable populations.

In this work, I will argue that the way the concept of vulnerability is used in the research ethics context is not as useful and appropriate as possible. Although there are circumstances under which special protections may be justified, the categorization of broad populations as vulnerable risks causing a number of harms both practical and conceptual. A central concern of this project is well framed by Martha Minow who asks, "When does treating people differently emphasize their difference and stigmatize and hinder them on that basis, and when does treating

people the same become insensitive to their differences and likely to stigmatize or hinder them on that basis?"[1]

I will argue that because the concept of vulnerability is insufficiently sensitive and specific, it fails to pick out those and only those who are in need of special protections. I will also argue that the label of vulnerability can stigmatize those who are labeled as such, and further that they may harmfully internalize that stigma. Finally, I argue that the concept of vulnerability fails to draw attention to the reason that individuals or populations are vulnerable, and that it therefore does not serve to initiate an attempt to address these underlying problems but rather focuses the attention on solutions which impact the vulnerable individual. At the same time, it is true that some people are susceptible to being harmed or wronged to a greater degree than others, and bioethics ought to be concerned with identifying and preventing these harms and wrongs. Therefore, ultimately, I will propose a way in which vulnerability ought to be conceptualized which would allow special protections to be put into place to protect individuals who are at an increased risk of experiencing harms, wrongs, or exploitation but which will not either force a label on individuals who are not at risk or further wrong individuals who are.

In the first of the sections that follow, I will describe the concept of vulnerability and explore how it is used in the regulation and guidance of research with human subjects. Then, the next section will articulate how current use of the concept in research fails to promote the goals of protecting so-called vulnerable populations from harms, wrongs, or exploitation. I will argue that, in fact, such use may cause additional harms to these already (potentially) vulnerable individuals. Finally, section four will discuss how vulnerability may be reconceptualized in a way that would avoid the harms and stigmatization which are presented by the current schema

[1] Minow, Martha. *Making All the Difference: Inclusion, Exclusion and American Law.* (Cornell University Press, 1991): 20.

for implementing special protections. In reconceptualizing vulnerability, special protections can be offered that would both be more effective at combating harms and wrongs that may result from research participation and avoid the harmful implications and stigmatization which are attendant in the way that the concept and label are currently applied.

2.0 'VULNERABILITY'

The term 'vulnerability' is frequently used in the areas of research ethics and research regulation. For instance, the United States Department of Health and Human Services' Office for Human Research Protections (OHRP) lays out defined groups of vulnerable populations subject to various special protections in the research setting. The label is intended to heighten awareness of particular individuals' or groups' susceptibility to harms or wrongs and also to trigger special protections of their interests and rights. In general, vulnerability is a very expansive concept used to signify varying types of weaknesses arising from different characteristics – physical or situational. "[T]he root of the concept of vulnerability lies in the possibility of physical harm. The term derives from the Latin *vulnus* (wound). In ordinary language, 'vulnerable' means 'capable of being attacked, harmed, or injured in some way.'"[2]

There are ways in which someone may be vulnerable which are ethically significant, as well as ways which are not of any ethical concern. Certain individuals, for instance, might be described as particularly "vulnerable to the flu." Although the term 'vulnerable' is being used in accordance with the above definition, the way in which the individual is capable of or susceptible to suffering such harm is not in itself morally relevant. In the morally relevant sense, the term

[2] Levine, Carol, et al. "The Limitations of "Vulnerability" as a Protection for Human Research Participants." *American Journal of Bioethics* 4, no. 3 (2004): 47.

'vulnerable' is used to note a susceptibility to being wronged or taken advantage of, or a heightened susceptibility which is the result of the relationship between a characteristic of an individual (e.g., being particularly susceptible to the flu) and the conditions present in the research context (e.g., being required to visit a clinic numerous times during flu season). The concept represents a concern for an individual's or population's lack of the usual level of ability to safeguard her or their own interests.

The recognition of a population as vulnerable may denote a number of ethical concerns. The need for special protections is invoked in cases where the individual or population is particularly susceptible to being harmed, exploited, or wronged (in ways other than exploitation). There are various characteristics which might cause individuals particularly "capable" of being harmed, exploited, or wronged – i.e., characteristics that make them vulnerable. Sometimes, as will be examined more fully below, the characteristics are features of the individual's external environment (e.g., impoverishment, lack of political power), and sometimes the characteristics are features of the individual herself (e.g., suffering a traumatic brain injury, being pregnant); furthermore, the characteristics can be more or less malleable (e.g., being a minor, suffering irreversible brain damage).

In research regulations, vulnerable categories of people are identified, and special limitations on their enrollment or conditions of their participation in research are imposed.[3] These categories identify groups of individuals who are believed to have limited decision-making capacity (e.g., cognitively impaired persons), to experience constraints on the voluntariness of their choices (e.g., prisoners), or to face harms of greater magnitude or probability than others as a result of participation in research (e.g., the greater harm that a person

[3] Coleman, Carl H. "Vulnerability as a Regulatory Category in Human Subject Research." *Journal of Law, Medicine and Ethics* 37, no. 1 (2009): 12.

with a stigmatizing health condition may suffer if the confidentiality of research records were breached).[4] Special protections, then, are designed to identify and compensate for these limitations in order to ensure that these individuals are enrolled in research only when their decisions to participate were truly voluntary, informed, and competently made, and that there are heightened protections considered that would compensate for the higher frequency or severity of harms experienced by certain populations.

2.1 VULNERABILITY AS A CONCEPT AND ITS USES

The concept of vulnerability is employed to signify an individual's or a population's susceptibility to being harmed or wronged.[5] The term vulnerability has appeared with a different significance than the one that is considered in this paper; that is, vulnerability has been noted by

---

[4] Office of Protection From Research Risks (OPRR). *Institutional Review Board Guidebook* (1993), Chapter VI: Special Classes of Subjects, *available at* http://www.hhs.gov/ohrp/archive/irb/irb_chapter6.htm (last visited April 1, 2011).; The details of the *Guidebook*'s origins will be covered in a later section. For now it will suffice to say that a rendition of the *Guidebook* was first developed in the early 1980's under contract by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research to help IRB members understand the principles and regulations that applied to research with human subjects. *Id.*, at Forward. A second version was prepared by the Office of Protection of Research Risks and Robin Levin Penslar, editor. *Id.* This version was last updated in 1993, and the Office for Human Research Protections (OHRP) indicates on its copy published to the internet: "Developments over the intervening years have made portions of the Guidebook information obsolete, while portions of the information remain valid. There is no errata document to indicate which information has been superseded. OHRP cautions users to verify the current validity of any Guidebook information before relying on the information in a program of human subjects protection." *Id.* The *Guidebook*'s section on "Special Classes of Subjects" is consistent with the current status of research regulations; and thus remains a relevant source of information on review of study protocols which involve vulnerable subjects.

[5] *See, e.g.*, Kipnis, Kenneth. "Vulnerability in Research Subjects: An Analytical Approach." In *The Variables of Moral Capacity*, edited by David C. Thomasma and David N. Weisstub, 217-231. Kluwer Academic Publishers, 2004.; "By definition, it is a distinctive precariousness in the condition of the subject: a state of being laid open to or especially exposed to something injurious or otherwise undesirable. A vulnerability is, so to speak, an avenue of attack.", *Id.* at 220.; *see also*, World Health Organization, Health Dimensions of Economic Reform (1992) available at http://whqlibdoc.who.int/hq/1991/57259_(part1).pdf (last visited April 18, 2011): 11.; "The concept of vulnerability has been widely used to denote a condition in which the physical and mental will-being required for a normal productive life is impaired and at constant risk. However, vulnerability in general usage includes any condition of exposure to hazards, risks and stresses." *Id.*

various thinkers to be an essential characteristic of the human condition.[6] Vulnerability in that broader sense signifies the human condition of being mortal, imperfect, dependent, capable of being harmed.[7] The concept of vulnerability, however, is more commonly used and thought of to signify a more narrow subset of individuals – those who are *particularly* prone to being harmed or wronged. This concept singles out those who are "more *deeply, variably* and *selectively* vulnerable to the action of particular others and the particular institutions on whom [they] come to depend for specific and often unavoidable purposes."[8]

In research regulations, the condition of vulnerability is ascribed to those groups who exhibit the diminished or complete lack of capacity to consent, dependence, or inequitable access to power or resources.[9] "Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests."[10] The concern for vulnerable populations, then, is their lack of ability – which may stem from incapacity, lack of power, or other characteristics – to ensure the protection of their own interests.

The term vulnerable is used in reference to individuals or groups who are particularly prone to being harmed or wronged because of: (1) a lack of decision-making capacity, (2) a particular inability to make a voluntary decision, or (3) a heightened rate or severity of harms which may befall that individual or group by her or their participation in research. The first two

---

[6] *See* Kottow, Michael H. "Vulnerability: What Kind of Principle Is It?" *Medicine, Health Care, and Philosophy* 7 (2004): 281-287., for a discussion on this point.
[7] *See, Id.*, at 282-3., citing the works of Hobbes, Mills, MacIntyre and Heidegger.
[8] O'Neill, Onora. *Towards Justice and Virtue: A Constructive Account of Practical Reasoning.* 2nd prtg. (Cambridge University Press, 1998): 192.
[9] Levine, *supra* note 2, at 45.
[10] Council for International Organizations of Medical Sciences (CIOMS). "International Ethical Guidelines for Biomedical Research Involving Human Subjects." 2002, available at http://www.cioms.ch/publications/layout_guide2002.pdf (last visited April 1, 2011).

uses refer to ways in which an individual's or group's decision-making power – a power which would serve to protect the individual's or group's interests – can be undermined so that they may be rendered particularly susceptible to being harmed or wronged. Vulnerable individuals or groups may be particularly susceptible either because they lack competence for any number of reasons, or because they may be particularly subject to undue pressure which would render their decision involuntary. Cognitively impaired individuals, for instance, are considered vulnerable. The label 'vulnerable' is applied to cognitively impaired individuals because of a particular characteristic – namely, a lack of cognitive ability which renders them susceptible to being physically harmed or taken advantage of. Minors constitute another group which is generally considered vulnerable because of their lack of competence.

An individual or population may also be labeled 'vulnerable' in instances in which undue pressure may be exerted on their decision-making in spite of their competence. For instance, prisoners are considered a vulnerable population within the research context because of their circumstances, not a lack of cognitive ability.[11] They are particularly susceptible to being harmed or wronged because they are wards of an institution and can easily be subject to undue pressures which undermine their ability to make informed, voluntary decisions. Students are another example of a population which might be considered vulnerable in a decision-making context because of the overwhelming potential for undue influence to be exerted and for their decision-making powers to be undercut.

Individuals may also be vulnerable in a sense that is not connected to decision-making ability – namely, by being particularly susceptible to harms which may result from the conduct

[11] At least not typically; set aside any arguments or evidence that incarcerated individuals typically have a lower socioeconomic status or education level. When prisoners are identified as a vulnerable population, the concerns are most typically about their status as institutionalized individuals.

of research (either normal research procedures or failures of research protections). Harms may befall them at a greater rate or they, in particular, may be exposed to more devastating harms than other individuals or groups. In short, certain populations or individuals can be particularly susceptible to harms which are a result of features encountered in the research process. Research involves the collection of data about individuals, sometimes sensitive medical information or other personal information. If a breach of confidentiality were to occur, some groups or populations may be harmed more gravely than others. For instance, HIV-positive individuals can constitute a vulnerable population because they would be much more gravely harmed by a breach of their medical data which identifies them as such than their HIV-negative counterparts, who would be unlikely to suffer any effect from a breach of information regarding their HIV status. Breaches of confidentiality may also affect individuals with as yet unexpressed genetic conditions more severely than those not at genetically increased risk, because they may be discriminated against in employment or in acquiring life insurance or may be stereotyped by others who may express their attitudes or opinions in harmful ways. These groups are more susceptible to being harmed or wronged by participation in research because particular adverse events which may occur would tend to harm them with more frequency or severity than others who don't share that particular characteristic.

In addition to different sources of vulnerability, an individual or group can be thought to be susceptible to different sorts of negative outcomes: (1) harms, (2) wrongs, or (3) exploitation. Although exploitation is actually a subset in the category of "wrongs," I will address it as its own category in this work because it is a particularly relevant and overwhelming concern which drives the need for the research protections and the use of the 'vulnerable' label in that context.

Prevention of harm is a major goal of bioethics, but what is meant by 'harm' is not always clearly defined. In this paper, the term 'harm' will be used in what has been described as its "ordinary language" sense; that is: "Ordinary language tends to distinguish between being harmed (in the broad sense of suffering an adverse effect, or the unreasonable *risk* of such an effect, on one's self- interest) and being wronged, that is having one's rights violated."[12] To be harmed is to be made worse-off. 'Harms,' for our purposes, will mean events which have an adverse effect on one's interests, but that do not necessarily violate one's rights.

Wrongs are actions which constitute a violation of an individual's rights, and are morally-relevant.[13] Wrongs frequently, but do not necessarily, make one worse-off. Harms and wrongs can thus occur independently (i.e., there can be harms that aren't wrongs, and vice versa), but they may also co-occur. There are many common examples of things that are harms but not wrongs, such as becoming ill from a virus, losing one's personal possessions in a natural disaster, or feeling mental displeasure at witnessing a gruesome traffic accident.[14] Although examples of wrongs that are not harms are harder to come by, they do exist. Someone who is (wrongly) lied to and thus modifies his behaviors but in a way that ultimately promotes his interests has experienced a wrong but not a harm. If you lie to me and tell me you like my dress, I may be wronged by being told a lie, but ultimately I am not harmed because it is not meaningfully adverse to my interests for you to dislike my dress, and further I may get a feeling of happiness or pleasure at thinking you do like it.

Instances of exploitation constitute a subset of wrongs, specifically those wrongs that involve taking advantage of another through an unfair agreement. Research tends to create

---

[12] Feinberg, Joel. "Harm and Offense." In *Encyclopedia of Ethics*, edited by Lawrence C. Becker and Charlotte B. Becker. New York: Routledge, 2001.
[13] *Id.*.
[14] *Id.*

concern about the exploitation of individuals, because research involves placing some people at risk for the benefit of others.[15] Because prevention of exploitation is a primary goal of the use of the 'vulnerability' label, it is important to have a detailed understanding of exploitation. According to Alan Wertheimer, exploitation involves three elements: (1) individuals who are exploited suffer some detriment or negative effect in an agreement (2) in which another gains, and (3) there is some defect or unfairness in the process by which the agreement took place.[16] Exploitation does not always require that a harm result to the individual who is exploited; the person being exploited can, in fact, be made better off by the exploitative agreement.[17] Exploitation, on this view, takes an "all-things-considered" approach to considering an individual's interests and determining whether or not she suffers a detriment or negative effect as part of an agreement.[18] An individual may suffer a wrong in an agreement when both parties gain (in contrast to their status if there is no agreement), but the proportion of the exploitee's gain is unfair compared to that of the exploiter.[19]

For instance, suppose that B is stranded on a deserted road (without a cell phone) in the middle of the night. Suppose that A drives by, notices B, and stops to see if B needs help. A offers B a ride back to town (15 miles away), but only if B agrees to pay A $200. A is driving the only car that has passed B in the matter of a two hour time frame, and B fears that if she does not accept A's offer it will be many more hours until someone else comes by. Reluctantly, B agrees to pay A for the ride. In this situation, B gains from the transaction. She gets a ride back to town and is no longer stranded. However, she suffers a wrong because she pays too high a

---

[15] Emanuel, Ezekiel, David Wendler, and Christine Grady. "What Makes Clinical Research Ethical?" *Journal of the American Medical Association* 283 (2000): 2701.
[16] Wertheimer, Alan. *Exploitation.* (New Jersey: Princeton University Press, 1996): 34.
[17] *Id.,* at 18-28.
[18] *Id.,* at 19.
[19] *Id.,* at 21-22.

price for what she gains. The transaction was exploitative despite the fact that B is made better off by no longer being stranded. B gains, but disproportionately to what she pays, and A gains, but the transaction was unfair. Therefore, although B did not suffer a harm, she was wronged by being exploited in this particular agreement. Individuals are wronged when they are exploited because they are taken advantage of in an unfair transaction.[20]

Research protections need to address concerns about exploitation because the research context necessarily involves a situation that presents the risk of exploitation. In research, (1) an individual is put at risk via an agreement to participate in research, (2) in which the agreement is designed primarily to afford potential benefit to another party (e.g., society through the increase of knowledge, or future patients through development of improved medical interventions. Individuals participate in research and thus assume certain risks, while the benefits of the research are not meant to accrue to those participating in the research, but rather to society as a whole.[21] What is critical is to ensure that the agreement to participate is not exploitative or does not take unfair advantage of participants.

The concept of vulnerability is designed to recognize individuals that are particularly prone to being harmed, wronged, or exploited and to draw attention to the conditions which render them vulnerable. It signifies concern about an individual's ability to protect her own interests. In the next section, the concept of vulnerability as situated within the context of research protections will be extensively explored.

---

[20] Wertheimer, *supra* note 16, at 34.
[21] Benefits that do accrue to research participants may be accidental, and are not part of the study design.

2.2 THE REGULATION OF RESEARCH AND THE CONCEPT OF VULNERABILITY

Oversight of research and research regulations emerged in the 20th century in the light of major human subject abuses and highly publicized tragedies which occurred in the course of research studies involving human participants.[22] The protections which apply to human research subjects come from a variety of sources and have materialized slowly over time. Although there were sporadic protections in place prior to the period following World War II,[23] the "Doctors' Trial" of 1947 marked the start of a more regular flurry of regulations applicable to research conduct. After the "Doctors' Trial"[24], in which 23 doctors and administrators in the Nazi regime were tried for their participation in highly unethical, disturbing, and torturous medical experiments on humans, the Nuremberg Code was developed to prevent similar abuses from happening in the future.[25] The Nuremberg Code, although never officially incorporated into American law, is generally considered the foundation for the research ethics guidelines and regulations that are in place today. In 1964, the World Medical Association (WMA) issued the Declaration of Helsinki which broadened the ethical obligations which attached to physicians to the area of research involving human participants.[26]

---

[22] For an excellent, and much more comprehensive than is presented here, look at the development of regulations for human research subjects protections and the historical context in which they were developed, *see* Faden, Ruth R., and Tom L. Beauchamp. *A History and Theory of Informed Consent.* Oxford University Press, 1986., in particular, chapters 5 and 6.

[23] *See,* Berg, Jessica W., Paul S. Appelbaum, Lisa S. Parker, and Charles W. Lidz. *Informed Consent: Legal Theory and Clinical Practice.* 2nd ed. New York: Oxford University Press, 2001., for an excellent timeline beginning with a research scandal in Prussia in the 1890s which sparked government-mandated consent obtainment for research.

[24] *US v. Karl Brandt, et al.* (1947).

[25] Heimer, Carol A., and JuLeigh Petty. "Bureaucratic Ethics: IRBs and the Legal Regulation of Human Subjects Research." *Annual Review of Law and Social Science* 6 (2010): 602.

[26] The Declaration of Helsinki, *available at* http://www.wma.net/en/30publications/10policies/b3/17c.htm (last visited April 1, 2011).

Because of the continued abuses of human research subjects in the United States,[27] the National Research Act[28] was enacted in 1974. The Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the Department of Health and Human Services.[29] The Commission worked for four years to develop a set of ethical principles to guide researchers in the biomedical and behavioral sciences conducting studies with human subjects, officially titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," but most commonly referred to as the "Belmont Report."[30] The three principles named by the *Report* are respect for persons, beneficence, and justice.[31] Although this report was issued merely as guidance and was based on ethical principles, the principles influenced the Common Rule,[32] which is enforceable and requires all research funded by the

[27] The most infamous of these abuses are probably the 1932-1972 Tuskegee study of untreated syphilis among poor black men and the 1963-1966 study in which students with mental retardation at the Willowbrook State School were injected with hepatitis as a condition for their admission for research purposes. *See*, Heimer and Petty, *supra* note 25, at 602.
[28] Public Law 93-348.
[29] *Id*.
[30] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. "Ethical Principles and Guidelines for the Protection of Human Subjects of Research ("The Belmont Report")." 1979, available at http://ohsr.od.nih.gov/guidelines/belmont.html (last visited April 1, 2011).
[31] *Id.*
[32] 45 C.F.R. §46, Subpart A.; Chapter 45, section 46 of the Code of Federal Regulations was drafted as the regulation governing research conducted or funded by the Department of Health and Human Services. By 1991, 15 federal agencies in total adopted Subpart A of these regulations to govern research studies involving human subjects, and so it became known as the "Common Rule." *See, e.g.*, Heimer & Petty, *supra* note 25, at 602.; Emanuel, Ezekiel, et al., "Oversight of Human Participants Research: Identifying Problems to Evaluate Reform Proposals" *Annals of Internal Medicine* 141 (2004): 282.; The agencies were free to adopt any or all (or none) of the subparts of 45 C.F.R. §46, but the majority have only adopted subpart A. Some agencies, such as the Department of Education (at 34 C.F.R. §97) have chosen to adopt other subparts of 45 C.F.R. §46 in addition to subpart A; the Department of Education has incorporated subpart D pertaining to special protections for research involving children. Other agencies have adopted the Common Rule, and also incorporated additional protections but using their own, independently-worded provisions (*see, e.g.*, 40 C.F.R. §26, which are the Environmental Protection Agency's regulations regarding research involving human subjects. They have instituted additional protections for research involving children and pregnant women, but they have drafted their own regulations.).

particular federal agencies that adopted the regulations which require studies involving human participants to be subject to review by an Institutional Review Board (IRB).[33]

Institutional review boards (IRBs) are the organizations charged with protecting human research subjects from harm; and they do so by reviewing proposed research and approving, requesting modification of, or disapproving research protocols in light of the complex regulations set forth in the Common Rule.[34] The regulations require that IRBs review and approve studies to ensure that their design follows the ethical principles before individuals are enrolled. IRBs are also charged with oversight of the ethical conduct of the study as it proceeds.[35] Although the Common Rule specifically charges IRBs with ethical review responsibilities, IRBs are largely left to interpret the regulations and to determine what criteria to consider and whether or not proposed studies fulfill the regulations and the *Belmont* principles. There is an abundance of literature on most aspects of research ethics and research review which might guide IRB members in their ethical analysis of proposed research.

An influential article in the research ethics literature examines seven requirements which could serve as a framework for determining whether or not a particular study protocol is in conformity with the guiding ethical principles generally recognized by the documents which govern human subject research.[36] The proposed study must: (1) be of social or scientific value; (2) conform to accepted standards for ensuring scientific validity; (3) provide for fair subject selection; (4) exhibit a favorable risk-benefit ratio; (5) be subject to independent review; (6) require the acquisition of informed consent; and (7) exhibit respect for potential and enrolled

[33] "Protection of Human Subjects," 45 C.F.R. §46 (2005).; In 1991, 15 federal agencies in total adopted 45 C.F.R. §46, subpart A, to govern research studies involving human subjects, and because of its widespread adoption, it has become known as the Common Rule.
[34] Maschke, Karen J. "Human Research Protections: Time for Regulatory Reform?" *Hastings Center Report* 38, no. 2 (2008): 20.
[35] 45 C.F.R. §46.109.; *see also* Maschke, *id*.
[36] Emanuel, et al., *supra* note 15, at 2701.

subjects.[37] The ethical values from which this framework was derived are: concern for a scarcity of resources, nonexploitation, justice, nonmaleficence, beneficence, public accountability, minimizing the influence of conflicts of interest, respect for autonomy, and respect for welfare.[38] Thus, the ethical framework which guides considerations of human subjects research is more robust than the three principles recognized by the *Belmont Report*, and it is this more exhaustive set of values which ultimately informs protection of human research subjects.

Some research regulations[39] and guidance provided to institutional review boards[40] lay out a very particular list of populations which are considered vulnerable. Eleven populations are considered vulnerable in the *IRB Guidebook*, a reference manual for IRBs, which incorporates the existing federal regulations with ethical considerations and offers IRB members a resource to consult when dealing with particularly difficult issues of ensuring the protection of human research subjects. The *IRB Guidebook* was drafted by the Department of Health and Human Services' Office for Protection from Research Risks[41] in consultation with numerous advisors to, as stated in the Preface, "provide precisely what its title is intended to denote: guidance. The *Guidebook* does not itself constitute regulations but rather has been prepared for the convenience and reference of IRB members and administrators"[42]

Perhaps because human subject research regulations and guidelines developed as a response to grave harms and wrongs, they are crafted to recognize that there are particular circumstances in which some people may be particularly prone to being subjected to those harms

---

[37] Emanuel, et al., *supra* note 15, at 2703.
[38] *Id*.
[39] "Protection of Human Subjects," *supra* note 33.
[40] *Institutional Review Board Guidebook*, Chapter VI: Special Classes of Subjects, *supra* note 4.
[41] The OPRR is the predecessor to the Office for Human Research Protections (OHRP) mentioned earlier. The OHRP has accepted the findings regarding research regulations and guidance found in the materials published by the OPRR. Office for Human Research Protections, "Policy and Guidance," *available at* http://www.hhs.gov/ohrp/policy (last visited April 18, 2011).
[42] *Institutional Review Board Guidebook*, *supra* note 4.

or wrongs, though the *Guidebook* does not focus on circumstances, but on groups of people. Chapter 6 of the *Guidebook* discusses protections for "Special Classes of Subjects."[43] The Preface states that this chapter "[p]rovides an analysis of the ethical issues that arise in research involving classes of particularly vulnerable research subjects."[44] It also makes reference to the fact that there are regulations in place for some of these "special classes of subjects," but not for others.[45] There are legal regulations in place governing the enrollment in research of "pregnant women, human fetuses and neonates,"[46] "prisoners,"[47] and "children."[48] However, the *Guidebook* recognizes that there are other classes of people who may be particularly vulnerable to harms or wrongs as research subjects and who could benefit from additional safeguards. The eleven populations named in the *Guidebook* are – (1) fetuses and human in vitro fertilization; (2) women;[49] (3) children and minors; (4) cognitively impaired persons; (5) prisoners; (6) traumatized and comatose patients; (7) terminally ill patients; (8) elderly/aged persons; (9) minorities; (10) students, employees, and normal volunteers; and (11) international research participants.[50]

The *Guidebook* and the Common Rule provisions reflect concerns about some of these groups' decision-making abilities, which are pertinent to enrollment decisions and informed

---

[43] *Institutional Review Board Guidebook*, Preface, *available at* http://www.hhs.gov/ohrp/archive/irb/irb_preface.htm (last visited April 1, 2011).
[44] *Id.*
[45] *Id.*
[46] 45 CFR §46, subpart B.
[47] 45 CFR §46, subpart C.
[48] 45 CFR §46, subpart D.
[49] The federal regulations (at 45 CFR §46) require special considerations be given to vulnerable subjects, and list only fetuses, pregnant women, human in vitro fertilization, prisoners, and children. The *IRB Guidebook*, by contrast, recommends further populations which may warrant special consideration. Under the heading "women," the *Guidebook* does narrow its focus to "women who are or may become pregnant," (*Institutional Review Guidebook*, *supra* note 4) and the special considerations are aimed at protecting the health of the (potential) fetus. The *Guidebook* does also make a note of the historic exclusion of all women from research, and (to the extent that it may safely be done) urges the inclusion of women within research subject populations so that they may benefit from the research findings as much as other populations.
[50] *Institutional Review Board Guidebook*, Chapter VI: Special Classes of Subjects, *supra* note 4.

consent, and sometimes recognize concerns unrelated to decision-making – namely that harms may accrue to individuals under certain circumstances more often or more severely than to others. Depending on the nature of the concern, the added safeguards may be implemented at any point in the research study process. When an IRB reviews a research proposal, it does not only review consent forms; IRBs are responsible for reviewing the entire study protocol including information about the scientific validity of the study, the exact procedures being used, the anticipated benefits or findings, the study's risk-benefit ratio, any advertisements for enrollment, eligibility and exclusion criteria, and subject recruitment procedures. When a study is likely to involve the enrollment of members of one of the eleven designated groups, it is recommended that special safeguards be instituted, although the form of those safeguards varies.

The ethical principle of respect for persons is exhibited by ensuring that autonomous individuals are treated as autonomous, and also that those who may lack the ability to make fully autonomous decisions have special protections put into place so that they are not used simply as a means to an end and so that their autonomy is respected to the extent possible.[51] According to the *Guidebook*, respect for persons requires that individuals be asked to give informed consent to participate in research. Informed consent has three elements: "information, comprehension, and voluntariness."[52] Individuals must be given enough information to make a voluntary, informed decision about research participation, including information about the study procedure, risks, any anticipated benefits, any alternative treatments available (if the study is therapeutic), and information about an individual's ability to withdraw from the study.[53] This information, secondly, must be given in a manner which the individual is able to understand, taking into

[51] Belmont Report, *supra* note 30.
[52] *Institutional Review Board Guidebook*, Introduction, *available at* http://www.hhs.gov/ohrp/archive/irb/irb_introduction.htm (last visited April 1, 2011).
[53] *Id*.

consideration any possible cognitive limitations and modifying the manner in which information provided accordingly.[54] Finally, consent must be voluntarily given, which means it must be given under circumstances "free from coercion and undue influence."[55]

The Common Rule offers a more robust description of the legal requirements of informed consent. Ultimately, the requirements can be distilled into eight basic elements: "(1) a statement that the study involves research, as well as a description of the research and its purposes; (2) a description of reasonably foreseeable risks; (3) a description of reasonably expected benefits; (4) disclosure of appropriate alternatives; (5) a statement about maintenance of confidentiality; (6) for research involving more than minimal risks, an explanation about possible compensation if injury occurs; (7) information about how the subject can have pertinent questions answered; and (8) a statement that participation is voluntary (i.e., that refusal to participate involves no penalties or loss of benefits)."[56] In addition to this information, certain potential subjects should also be "given information regarding: (1) unforeseeable risks; (2) circumstances under which the subject's participation will be terminated; (3) additional costs that the subject may incur; (4) the consequences of a subject's decision to withdraw; (5) the dissemination of findings developed during the study that relate to a subject's willingness to continue; and (6) the approximate number of total subjects."[57]

Sometimes the deficits which create concerns about being able to give voluntary, informed consent can be remedied, cured medically, or will resolve on their own. Unintelligible consent forms, for instance, may be remedied and rendered intelligible by rewriting them at a reading level that allows individuals with low literacy or even cognitive impairment to

---

[54] *Institutional Review Board Guidebook*, Introduction, *supra* note 52.
[55] *Id*.; "IRBs should be especially sensitive to these factors when particularly vulnerable subjects are involved." *Id.*
[56] Berg, et al., *supra* note 23, at 256.
[57] *Id*.

understand them. A revised consent form could, in some instances (e.g., when enrolling persons with mild cognitive impairment), allow fulfillment of the information and comprehension requirements of informed consent. Concerns about competence may in some cases be assuaged by understanding the cognitive level of these individuals and ensuring that they receive information about research participation in a manner which they understand and can use to make an informed decision, thus respecting their autonomy. An individual whose competence fluctuates may be approached for enrollment only during periods where her competence is unhindered, or an individual with a mood disorder which may prevent her from fully considering her interests when making a decision could provide informed consent to enroll once medication restores her capacity to make a fully-considered decision.

Concerns about undue pressure being exerted on prospective subjects might also be alleviated through the use of other safeguards in the enrollment process. For instance, if the subject is being enrolled in a clinical study conducted by her professor, the study protocol may require that a third party present and explain the consent form as well as the information necessary for informed consent to the potential subject. This third-party involvement may decrease the pressure which may be felt by the potential subject-student the subject would feel no pressure to oblige that disinterested third-party. Another safeguard involves deciding where enrollment for the study will take place and advertisements will be placed. By limiting the publicity of a study or its location, different populations may be attracted to participate. If one concern about the study design is that the payment, while fairly scaled to the participation risks, may serve as an undue inducement to get certain economically disadvantaged populations to participate, one safeguard may be that the enrollment is scheduled to take place in a neighborhood not easily accessible to public transportation and thus less accessible to those

populations. Another safeguard may be to limit the advertising mechanisms; perhaps no advertisements would be taken out in the free city paper or placed in neighborhood health clinics which tend to serve economically disadvantaged populations.

Beneficence requires that when human subjects are involved, the risks of the research be minimized and the benefits be maximized.[58] This principle is upheld by IRB members when they evaluate the scientific merit of proposed research and require both that the study have a solid scientific foundation and that it addresses a scientifically or socially valuable question (e.g., the potential to increase generalizable scientific knowledge or afford therapeutic benefit). Study proposals must also show that the participation of human subjects is required to gain this knowledge, and when the study involves the enrollment of vulnerable populations, their participation must also be specifically justified.[59]

Finally, the principle of justice requires that the benefits and burdens of research participation are distributed fairly across individuals and populations.[60] Individuals must be chosen for participation fairly; they should not be enrolled because they are easily available or because the researcher feels they are less worthy as human beings and is thus more willing to impose the risks and burdens of research upon them.[61] Furthermore, the principle of justice requires that some populations are enrolled in research only under certain conditions (e.g., prisoners may only be enrolled when the study is particularly aimed at ameliorating a condition particular to the prison population and has been reviewed by a prisoner advocate).[62] This is a matter of justice because it ensures that, in reference to the given example, prisoners are enrolled

---

[58] Belmont Report, *supra* note 30.
[59] *Institutional Review Board Guidebook*, Introduction, *supra* note 52., "[T]he appropriateness of involving vulnerable populations must be demonstrated[.]" *Id.*
[60] Belmont Report, *supra* note 30.
[61] *Institutional Review Board Guidebook*, Introduction, *supra* note 52.
[62] *Id*.; *see also* 45 CFR §46, Subpart C.

in a study for which they as a population will receive maximal benefit and controls the amount of burden placed on them as a population. It prevents researchers from seeking to enroll prisoners simply because they are an easily accessible population who are living under controlled conditions (e.g., controlled diet, controlled schedule), thus thrusting a large amount of research burdens on prisoners as a population, and not in proportion to their representative numbers in society.

Vulnerability in the research context is a concept used to signify a group's particular susceptibility to being harmed, wronged, or exploited. Special protections are put into place such that the research study is conducted in accordance with established ethical standards and also with regard to these populations' particular susceptibilities. The goal is to recognize individuals' potential inability to make a voluntary, informed decision due to decreased capacity or propensity to suffer from undue pressures, or to recognize their propensity to suffer more severe or more frequent harms when participating in research. Although the special protections may be justified and in accordance with the ethical conduct of research, as the section below will explore, the current framework which governs the application of considerations of vulnerability inadequately offers these protections and also may cause particular harms to those who are members of the groups labeled as vulnerable.

3.0 NEGATIVE IMPLICATIONS AND HARMS OF THE VULNERABILITY LABEL

The special protections implemented in response to identification of a population as vulnerable are designed to benefit such populations and protect their interests. While the safeguards do afford some benefit or protection of their interests, the safeguards and the fact of being labeled as a vulnerable population (or a member of a vulnerable population) may also have some negative consequences. These negative consequences may arise within the research context or outside of it. Being a member of a population considered to be vulnerable may reduce or remove one's opportunity to make a choice to participate in research. In some situations this may be appropriate; but, as I will further argue below, in some cases the label of vulnerability is either applied where it should not be, or rests upon exaggerated concerns regarding the voluntariness or competence of an individual's decision-making and inability to protect her own interests. Individuals who belong to the vulnerable populations may not only be harmed by sometimes blanket exclusion from research, but they may also be harmed when they are subject to special protections solely on account of their identity as a member of a vulnerable population when they in fact do not possess the worrisome characteristic or situational features which render other individuals in that population vulnerable.

Other harms and negative effects of employing the concept of vulnerability as it is usually implemented include, as I shall argue, further disadvantaging groups that are already disadvantaged, and the ascription of particular characteristics to individuals who are members of

vulnerable populations with the result that many of their decisions may become automatically discounted or the people themselves may be stigmatized or disrespected. In the research context, the concept is applied as a label, and it is describes the vulnerability as entirely situated within the individual. There is no focus on the surrounding actors, institutions, and circumstances. Conceptualizing vulnerability in this way and then applying it as a label to groups of people can serve to promote a more global sense of lessened self-worth among individuals who are members of so-called vulnerable populations.

3.1 THE LABEL 'VULNERABLE' IS INSUFFICIENTLY SPECIFIC AND SENSITIVE, AND CREATES PROBLEMS OF JUSTICE

In this section I argue that because the concept of vulnerability is insufficiently sensitive and specific, it fails to pick out those and only those who are in need of special protections. This failure leads to problems of injustice. First, the way that the guidelines are formulated may lead to some nonvulnerable individuals being overprotected and may neglect to protect some individuals who actually are in need of these special protections. The result is an injustice – namely, a failure to treat like cases alike, or to treat similarly situated prospective subjects similarly.

Labeling entire populations is not sufficiently specific. The *Guidebook* names groups, not individuals or characteristics, and thus can result in individuals being subject to special protections or excluded from participation in research who should not be. Moreover, the way vulnerability is conceptualized as applying to rather easily identifiable populations (e.g., fetuses,

prisoners, the cognitively impaired) is insufficiently sensitive. In other words, this approach fails to identify all those individuals who are particularly susceptible to harms and wrongs by their participation in research. By focusing on the supposed vulnerability of *groups*, similarly vulnerable individuals who do not fall within one of the identified populations will not be afforded special protections. These failures of specificity and sensitivity create an issue of justice; relatively similarly situated individuals are not treated alike within research regulations and guidance, and thus within research itself.

The identification of vulnerable populations in research creates a system of categorization which uses a label which is not sufficiently specific to offer adequate protections to those human research subjects who truly are highly susceptible to harms or wrongs. The categories set out in the *Guidebook* and elsewhere function to identify *groups of people* ("minorities," "women," "Special *Classes* of Subjects") who may be more likely to possess the worrisome traits or find themselves in the troubling contexts which render the voluntary and informed nature of their decisions suspect. Because of these broad categories, the current schema is prone to producing both false positives (and false negatives, which will be addressed later) when identifying those who are in need of added protections. The result is both a failure to afford benefit and promote the welfare of prospective subjects, and cases of formal injustice.[63]

Relying on broad categories is a misstep in two ways: first, it assumes that individuals in each of these populations share the characteristic which gives rise to the heightened susceptibility to harms or wrongs; and second, it assumes that individuals who are members of these groups will be easily identifiable as such and thus will be subject to the developed special protections. While some vulnerable populations necessarily share the characteristics which

[63] Beauchamp, Tom L., and James F. Childress. *Principles of Biomedical Ethics.* 6th ed. (New York: Oxford University Press, 2009): 242.

render them vulnerable (e.g., all cognitively impaired individuals lack competence to some degree), others do not (e.g., not all minority research participants may face language barriers). Moreover, even among those populations who share a characteristic, they may not share it to the same degree. Cognitively impaired individuals, for instance, may still be competent to make some decisions, while incompetent to make others.[64] Some individuals who are only slightly cognitively impaired may be able to provide voluntary informed consent to enroll in a research study if given special attention during the informed consent process; however, because of the way the label of vulnerability frequently works – i.e., to exclude an entire vulnerable population – they may sometimes be precluded from having that opportunity.

Exclusion of a population from research is troublesome because if individuals with particular characteristics are systematically excluded from study, the findings of research will not be generalizable to them. So, the population may not benefit from research findings. As in the case of safeguards mentioned above which may involve limiting advertising mechanisms such that they are not taken out in free papers or placed in low-income medical clinics, the problem is that these studies will then tend to enroll a non-representative research sample. The application of the special protections across a broad population without regard to the variations among individuals is also troublesome when it leads not to outright exclusion from research, but rather to the enactment of special protections for both the individuals who do and do not require them. The establishment of a special informed consent process which requires all individuals labeled "cognitively impaired" to undergo a special, lengthy informed consent educational session and

[64] Competence is a relational concept; thus the answer to whether or not one is competent must depend on the decision being made. An individual may be deemed competent when the decision in question is whether he would prefer to ride his bike to work or take the bus, but may be deemed incompetent to make a decision about whether or not to participate in research. *See* Buchanan, Allen E., and Dan W. Brock. *Deciding for Others: The Ethics of Surrogate Decision Making.* (New York: Cambridge University Press, 1990): 18-23.

then establish their understanding by taking a quiz or performing some other action may be unnecessary and demeaning to those cognitively impaired individuals labeled as such but who did not lack the competence to undergo a more brief informed consent procedure used to enroll those individuals not categorized as cognitively impaired. This, and similar other situations, are examples of the false positives which may occur under the current framework, especially, though not exclusively, where perceived vulnerability leads to wholesale exclusion.

The current framework for addressing vulnerability can also produce false negatives. There are some individuals who could benefit from added protections while enrolling or participating in research, but who are not obviously included in or identified as members of the populations set out by the *Guidebook*. Therefore, the current schema fails to adequately protect some individuals who are in need of these protections as they are susceptible to being harmed or wronged in the ways with which the research regulations are concerned. This is a problem of the lack of sensitivity of the label. For instance, there is no category of vulnerable populations which would include poor white males. Although minorities are identified as a vulnerable population, and one concern listed in the *Guidebook* is that they may be particularly susceptible to facing undue pressure to participate in research due to financial motivations, there is no category which addresses this concern as applied to nonminority individuals. Therefore, although destitute individuals of any race may possess the kind of economic motivation that renders the voluntariness of their decision-making suspect, they may fail to be identified under the current scheme.

IRBs were meant to use the guidelines regarding vulnerable populations as a way to consider the ration of risks and potential benefits presented by a research study and to consider implementing greater safeguards in the research enrollment process and during the conduct of

research. The implementation of added safeguards can help to ensure voluntary, informed consent is given by prospective subjects; however, when instituting these safeguards is predicated on the labeling of a population as vulnerable, unintended negative consequences can arise for prospective research subjects and for other members of the population. If the practical goal of the *Guidebook* is to provide guidance to those involved in the decision-making process to avoid unduly harming or wronging particular groups, then this goal is not being met by the current scheme employing the label of vulnerability.

Further, the label 'vulnerable' does not focus attention on the different ways in which various individuals are vulnerable. The *Guidebook* uses categories which signify 'vulnerable *populations*,' not 'characteristics which may render an individual or group vulnerable.' For instance, the *Guidebook* lists "elderly/aged persons" as a vulnerable population.[65] However, the concern about the particular susceptibility of members of that population to being harmed or wronged is not directed necessarily at the individuals' ages. What renders that 'population' vulnerable is the fact that many elderly may suffer cognitive impairments or be institutionalized.[66] Therefore, the 'vulnerability' is expressed as a function of age across a population; however, the actual concern is for particular characteristics which may exist among the elderly, but are varied between individuals and are not a necessary feature of aging itself. Because a single label ('vulnerable') is applied to populations where the concerns are varied – a lack of competence, a circumstance of undue pressure, both, or even other circumstances rendering these groups more prone to harms or wrongs, the label fails to draw attention to what it is that renders a particular individual vulnerable, and thus she may fail to be offered protections.

---

[65] *Institutional Review Board Guidebook*, Chapter VI, *supra* note 4, at Subpart 8.
[66] *Id*.

By applying one label across all of these various situations, the true concern which justifies the enactment of additional protections is obscured.

Another concern is that by labeling categories of people as 'vulnerable,' and by identifying vulnerable individuals by their characteristics which make them part of one of the enumerated populations, it is seemingly suggested that they would benefit from the same kind of protections when in reality that is not the case. Considering the various ways in which these groups are vulnerable, and what they are vulnerable to, it is clear that one protection mechanism is not appropriate across several groups, just as a single mode of protection may not be appropriate across all individuals – even those who are vulnerable – within the group. For instance, while a modification to the language in the consent form and the educational level at which that information is conveyed might be appropriate to ensure mildly cognitively impaired persons can give adequate, voluntary, informed consent, a simple modification of consent language will not necessarily serve to satisfactorily protect terminally ill patients or prisoners.

Thus, the label vulnerable as it is currently used, employing a "subpopulation framework,"[67] lacks specificity and may result in the over-protection of individuals who are not in fact vulnerable. The label is also not sensitive enough and may result in a failure to identify some individuals who are in need of protections, and to adequately offer protections to those who do. There are worrisome practical results from these labeling issues – populations may be excluded from research participation, and therefore potentially from the benefits, those who are not in need of protections to them, which may be demeaning and also pointless. These two concerns create a problem of formal justice – relevantly similarly situated individuals in the

[67] *See, e.g.*, Grady, Christine. "Vulnerability in Research: Individuals with Limited Financial or Social Resources." *Journal of Law, Medicine and Ethics* 37, no. 1 (2009): 19-27.; Luna, Florencia. "Elucidating the Concept of Vulnerability: Layers Not Labels." *International Journal of Feminist Approaches to Bioethics* 2 (2009): 121-139.; Kipnis, *supra* note 5.

research context are failed to be treated alike. There are also other negative effects of the application of the label 'vulnerable' to populations which occur outside of the research context. They will be explored in the next section.

3.2 CONCEPTUAL CONCERNS REGARDING VULNERABILITY AND THEIR NEGATIVE EFFECTS

In addition to problems created within the research context by the labeling of broad populations as vulnerable, the concept of vulnerability itself raises conceptual and potential practical problems. The way the label is defined and applied can have a number of negative effects on members of the populations to whom the label is applied. First, labeling populations – and by extension, members of the population – as vulnerable implies that the reason for their vulnerability is integral to the individual and her situation and immutable. Situating the vulnerability within the individual, instead of identifying it as a feature of her circumstances or in her relationship with others, has negative consequences that parallel those associated with labeling individuals as disabled. This parallel is explored below. Second, the labels in the research context do not invite anyone – researchers or others – to delve into the source of the vulnerability. Therefore, it is difficult to conceptualize a solution or safeguard within the decision-making and enrollment processes which would address the underlying causes of vulnerability in order to ensure that each of these individuals has her particular form of vulnerability addressed, the competence of her decision-making process ensured, or the voluntariness of her decisions bolstered. The combination of these two problems create a third: once the characteristic of the population is essentialized, the source of the vulnerability ceases to

be viewed as a problem capable of redress. Once the label of vulnerability is affixed and essentialized, the desireability of conducting research with members of such populations ceases to exert pressure to address resolvable sources of vulnerability in order to enable their participation in research. The underlying source of the vulnerability – e.g., poverty or illiteracy – gains no support for redress from the research enterprise.

The way that the *IRB Guidebook* and other research regulations treat human subject protections for vulnerable populations tends to ascribe the vulnerability to the individual, as part of herself and her situation; an immutable characteristic and a deficiency. By listing classes of people, (e.g., "women," "prisoners," "elderly/aged persons"), the guidelines are identifying those individuals who are members of a questionably identifiable population as vulnerable. This label does not speak to the source of the vulnerability. The guidelines could identify various *sources* of vulnerability, or various *circumstances* which might bring about undue pressure or heighten susceptibility to being harmed or wronged. For instance, the guidelines could articulate a need for heightened protections in studies enrolling participants where the participant population is particularly prone to coercion from an authority figure or individual who has control over them. Or the guidelines might suggest that additional safeguards be enacted when enrolling subjects for a study where the potential subject population is particularly prone to undue pressure because of economic circumstances (perhaps the study protocol has some sort of requirement which would overwhelmingly exclude the enrollment of participants with steady full-time jobs).

Instead, the *Guidebook* focuses on the *populations* of individuals who might be likely to face undue pressure, a lack of competence, or a particular susceptibility to being harmed or wronged. This naming of populations both conceptually situates a deficiency in the class of individuals named, and also suggests that the solution be applied to that class of individuals as

opposed to modifying the surrounding circumstances or actors. For instance, one of the concerns about the use of prisoners as human subjects is the issue of whether or not "confidentiality of participation and of data can be adequately maintained in the prison."[68] Prisoners, while being 'vulnerable' in the definitional sense because they are facing a heightened susceptibility of being harmed and/or wronged by a breach of confidentiality, are not vulnerable because of any characteristic that is integral to each of their individual beings. The *Guidebook* and behavior of IRBs, however, apply protections to that class of individuals by speaking of them as 'vulnerable' and by restricting their opportunity to participate in studies, rather than addressing the insecurity of confidential study information to enable them to participate without incurring heightened risk.

When a population is identified as vulnerable, modifications may take place in the study protocol, but those modifications are generally implemented by affecting the opportunity or the ability of individuals who are members of the named vulnerable population to give consent to participate in the study. Whether the protection is in the form of a modified consent form, a refusal to enroll members of that population, or simply heightened scrutiny during the decision-making process for members of the identified population, the net effect is always on their ability to give consent to participation in research by which others will abide. It is not suggested, for example, that prisoners be permitted to enroll in a study once the data-keeping methods of the prison are bolstered. Other issues are less clear, but ultimately it tends to be the case that the additional safeguards are directed in a way that impacts the populations' opportunity or ability to give consent and enroll in the research study. For instance, monetary compensation is discussed under the heading of 'students, employees, and normal volunteers.'[69] The *Guidebook* reads:

---

[68] *Institutional Review Board Guidebook*, Chapter VI, *supra* note 4, at Subpart E.
[69] *Id.*, at Subpart 10.

> In research involving normal volunteers, particularly where the research involves more than minimal risk, IRBs must ensure that any monetary payments to subjects are not so great as to constitute an undue inducement. This issue may be particularly difficult for IRBs to deal with. Since subjects who volunteer to participate in such studies are usually compensated for their time and discomfort, IRBs should seriously scrutinize the payment schedules to ensure that any compensation offered is commensurate with the time, discomfort, and risk involved. Even so, where a research procedure involves serious discomfort and/or the real, though slight, possibility of serious harm (*e.g.*, studies that involve the insertion and positioning of catheters in veins or the heart), one can easily imagine that the motivation of persons who volunteer to participate may be monetary. IRBs should pay particular attention to the proposed study population and whether or not it may comprise persons who are likely to be vulnerable to coercion or undue influence, such as persons who are educationally or economically disadvantaged. The federal regulations require that IRBs employ special safeguards under such circumstances.[70]

Essentially, the *Guidebook* does note that monetary compensation must be reviewed for each study to ensure that it is appropriate and commensurate with the time and risk the study involves; monetary payments should act as reimbursements to the subjects but should not be so great as to become inducements.[71]

There are, however, some studies where the monetary value of these individuals' participation is great because the time and risk involved in study participation is great. In these cases, the monetary payment for participation cannot necessarily be lessened and still be fair. However, in such cases a large payment may become an undue inducement to those populations who are economically disadvantaged. Under these circumstances (the compensation is justifiably large and must not be reduced, and the study may attract economically disadvantaged applicants), the safeguards are again directed toward, and have an impact on, the 'vulnerable' population and their ability to participate in the study by giving informed consent. For instance, in one chapter of *The Oxford Textbook of Clinical Research Ethics* which discusses research involving economically disadvantaged participants, it is noted that poor individuals can be

[70] *Institutional Review Board Guidebook*, Chapter VI, *supra* note 4, at Subpart 10.
[71] Amdur, Robert J., and Elizabeth A. Bankert, *Institutional Review Board Member Handbook*. Jones & Bartlett Publishers, Inc. 2007.

vulnerable to undue financial inducements but should not be considered, on that basis alone, incapable of making decisions which protect their own interests.[72] However, the suggestions for added safeguards that may be considered when this population may enroll in research include limiting recruitment of economically disadvantaged individuals to only minimal-risk studies, applying "special scrutiny" to the decisions of economically disadvantaged individuals to participate in research, careful development and heightened monitoring of the informed consent process, and changing the setting of research such that economically disadvantaged individuals would be less likely to enroll or more likely to receive better attention.[73] All of these suggested special protections impact the ability of the economically disadvantaged to give consent to participate in research.

The way the label of 'vulnerability' is applied tends to suggest that the vulnerability which impairs the capacity to make decisions, undermines their voluntariness, or makes the individuals more susceptible to harms or wrongs, is somehow essential and immutable – integral to the individual and her situation, and unable to be changed. The conceptualization of vulnerability in this way can raise conceptual concerns which parallel much of the discourse surrounding the definition of "disabled" individuals, and the social construction of disability. In this context, some argue that the way disability is defined and conceptualized situates the deficiency entirely within the individual and fails to acknowledge that many or most of the disadvantages and limitations experienced are the result of the relationship between the disabled

---

[72] Levine, Carol. "Research Involving Economically Disadvantaged Participants." In *The Oxford Textbook of Clinical Research Ethics*, edited by Ezekiel J. Emanuel, Christine Grady, Robert A. Crouch, Reidar K. Lie, Franklin G. Miller and David Wendler. (New York: Oxford University Press, 2008): 435.

[73] *Id*.; There are also further inducements that are discussed which would make it more feasible for economically disadvantaged populations to participate in research (e.g., provision of childcare, relocating the research setting) if their participation was deemed necessary *and* if they are able to pass the heightened enrollment scrutiny. *Id.*

individual and her social and physical environment.[74] While some features of the individual's disability may indeed be biological facts and thus unalterable – e.g., blindness, deafness, or impaired mobility – features of the environment might be altered to eliminate or reduce the disabling result. Furthermore, the way disabled people are thought of and defined contrasts the individual's abilities against a "normal" scale, which may seem to reinforce the disrespectful implication that there are two classes of citizens: the normal and the less-than-normal.[75] In much the same way, the definition of vulnerability and the way that vulnerable individuals are currently identified fails to situate the deficiencies within the consent process and its broader social context; rather, the label ascribes to individuals a particular label or status noting their *inability* to participate in the consent process and make truly voluntary or competent decisions to enter into contracts or safeguard their own wellbeing against the possibility of harms or wrongs. In the case of vulnerability that does not affect individuals' abilities to give informed consent, but is associated with other concerns about research participation, the criticism is similar. Instead of conceptualizing the heightened risks these individuals face by participating in research as a result of features of the research institution itself, the vulnerability is connected to that feature of the individual which causes them exposure to the heightened level of risks.

The theory of the "social construction of disability" argues that disabled individuals are disabled less by the biological facts of their bodies and more by the social and cultural context in which they find themselves.[76] Definitions of disability are informed by a particular society's attitudes and expectations about the abilities of individuals and what it considers "normal" in

---

[74] *See, e.g.*, Mike Oliver, *Defining Impairment and Disability: Issues at Stake, in* Bury, Michael, and Jonathan Gabe. *The Sociology of Health and Illness: A Reader.* (New York: Routledge, 2004): 277.
[75] Young, Iris Marion, *Justice and the Politics of Difference.* Princeton: Princeton University Press, 1990.; in particular, pp.40-65 and 141-147.
[76] Although this is a widely argued-for concept, *see, e.g.*, Wendell, Susan. *The Rejected Body: Feminist Philosophical Reflections on Disability.* New York: Routledge, 1996., for a very thorough argument.

terms of abilities and performance.[77] The definition of the disability, and also its severity, are all constructed by social and cultural constraints and norms, rather than by particular facts of biology.[78] Furthermore, although there are some valid practical reasons to define which individuals are 'differently-abled' – we can offer protections and opportunities which address limitations otherwise placed upon them – some argue that there are other agendas behind defining "disability," particularly in the way that it is currently done.[79] If the only reason for defining disabled people was to offer them accommodations or protections, there would be no category of "disabled people;" everyone's abilities would be considered and everyone would be offered these protections and accommodations that would permit them to develop their full potential and be fully participating members of society.[80] The category of "disabled individuals" as it is currently defined and applied is both fails to identify everyone who is in need of these protections or resources and fails to identify what protections are needed.[81]

A similar argument can be made about the label of 'vulnerability.' The label functions much the same way as labeling someone as 'disabled' does. It ascribes the difference in abilities and failures of functioning entirely to the individual. If a disabled individual is unable, for instance, to open a heavy door, it is considered a feature of her disability and not a feature of society (i.e., the way we construct doors) which creates her inability to enter a particular room. If an individual is unable to give voluntary consent because she is particularly susceptible to undue pressure as an institutionalized elderly woman, it is not conceptualized as features of her situation which are causing the susceptibility, but rather her own dependence and frailty. Also,

---

[77] Wendell, *supra* 76, at 32-33.
[78] *Id.*, at 46.
[79] *Id.*, at 33.
[80] *Id*.
[81] *Id*.

while there is some basis in fact for the need for protections of human research subjects from being harmed, wronged, or exploited, the categorization of 'vulnerable populations' does not appropriately define who is in need of these protections. If the only concern was not permitting those who are susceptible to harms or wrongs be harmed or wronged, then the protections would take each individual's interests and circumstances into account, and protections currently considered special would be offered to all on the basis of considering each person's own susceptibilities. Furthermore, the protections that would be offered would also be more customized to the particular individual's needs – to what is rendering them more highly susceptible to harm or exploitation in any particular instance.

Finally, labeling someone as 'vulnerable' can have the same kind of effects that labeling someone as 'disabled' does. The label may help to define them or their identity. The label may lead them to feel stigmatized, which will be discussed in the next section.

3.3 STIGMA AND INTERNALIZED STIGMA

Seeming to locate the problem in the vulnerable individual leads to other ways, beyond the research context, that individuals are made worse-off. Individuals who are labeled as vulnerable may become viewed by others as particularly weak or dependent. Furthermore, they may become stigmatized by this conceptualization, which in turn could lead to a general discounting of their decision-making capacity and heightened scrutiny of their decisions, perhaps in nonresearch contexts. They may become viewed as lesser individuals; and in instances where this stigmatization is so pervasive, the so-labeled vulnerable individuals may internalize this

view of themselves as weak or lesser and thus accept a more global sense of frailty, weakness, or inability to make decisions which protect their interests.

Being vulnerable implies weakness, frailty, and dependence. Ascribing these characteristics to individuals is potentially demeaning and stigmatizing. Because the vulnerability framework in research protections situates the vulnerability within the individual subject, not relationally or situationally, being identified as vulnerable reifies and essentializes the condition of vulnerability making the trait of vulnerability more real and immutable than it may actually be.

Within American society, vulnerability may be particularly stigmatizing. [82] There is a particular stigma that attaches in this society to individuals who are seen as weak or dependent. Being unable to "pull oneself up by the bootstraps" or "make it through" on one's own creates an attitude of disdain among others. One of the reasons that being vulnerable is so negatively stigmatizing is that people tend to engage in what Iris Marion Young terms "dyadic thinking."[83] Dyadic thinking conceptualizes social relations in terms of power relations between dominant and subordinate groups.[84] The label of "vulnerable" creates an "Other."[85] The label sets up a dyadic relationship – an "us" and a "them."[86] Those in the dominant group oppress – at least in their own minds, if not in fact or action – the subordinate groups, judging those individuals as different and inferior.[87] Not only are the Others deemed different and inferior, but their experiences and worldviews tend to be discounted.[88] Because those in the dominant majority

---

[82] Tronto, Joan. *Moral Boundaries: A Political Argument for an Ethic of Care.* Taylor & Francis, Inc., 1993.; in particular pp.101-124 and 161-164.
[83] Young, *supra* note 75, at 41, 58-60.
[84] *Id.*.
[85] *Id.*
[86] *Id.*
[87] *Id.*, at 60.
[88] *Id.*

have greater control over social goods and tend to dominate the creation of norms and culture, the experiences of the Others in a society are discounted because they do not conform to the prevailing cultural norms and experiences.[89] When this occurs, these vulnerable Others may be ultimately viewed negatively by those in the majority in contexts completely removed from the initial setting that originated the label, in this case, research, or other decision-making contexts in which the label of vulnerability is applied. Because of the value placed on being independent and capable in this society, in virtue of dyadic reasoning, the state of being vulnerable presents a particular threat. The label prompts a more global sense of lessened worth of the so-called vulnerable individual. Being labeled as vulnerable, then, creates this stigma and is potentially harmful to those labeled as such.

Moreover, if a condition is sufficiently stigmatizing – that is, if a condition results in substantial shunning and disrespect by others – a person with that condition may internalize the stigma and come to think of herself as a lesser individual. The label of 'vulnerable' as it is ascribed to entire groups may be alienating or dehumanizing for those who have never felt vulnerable or particularly prone to exploitation by virtue of their membership in that group. Being defined as a member of a vulnerable population may serve to inform and distort an individual's perceptions of her own experiences and self-worth. In other words, the external stigma enacted by the "normal" in society may then become internalized by the individuals who are labeled as vulnerable. Those who are labeled as the "Others," who are stigmatized by their perceived deficiency or shortcoming from which they must be protected, may then internalize

[89] Young, *supra* note 75, at 60.

those negative stereotypes of themselves and begin to enact them or exhibit them where before they had not.[90]

Some evidence of this internalization, acceptance, and enactment of these characteristics associated with the label of vulnerability may be extrapolated from the social science literature regarding self-fulfilling prophecies.[91] Self-fulfilling prophecies occur when social beliefs lead to their own fulfillment; individuals become aware of a belief and adopt behaviors which conform with it.[92] The actions and behaviors of the stigmatized individual, in turn, serve to justify and maintain the initial stigmas.[93] Those who are stigmatized by being labeled as vulnerable may begin to enact behaviors and exhibit characteristics of weakness, frailty, and an inability to protect their own interests. The traits of the stigma become reified and the stereotypes are reinforced.

Although there may be sufficient stigma attached to members of many of these vulnerable populations (e.g., women, minorities, the elderly) in virtue of their membership in these historically stigmatized groups, the further labeling and stigmatizing associated with vulnerability is still troublesome. The stigma associated with vulnerability may serve to reinforce the stigma that these groups already experience. The reinforcement of the stigmatization of these social groups, further reinforced through self-fulfilling prophecies, is particularly troubling when the stigma is imposed by the research context. The stigma of being

---

[90] *See, e.g.,* Sayles, Jennifer N., and et al. "Development and Psychometric Assessment of a Multidimensional Measure of Internalized HIV Stigma in a Sample of HIV-Positive Adults." *AIDS Behavior* 12, no. 5 (2008): 748-758.; Ritsher, Jennifer Boyd, Poorni G. Otilingam, and Monica Grajales. "Internalized Stigma of Mental Illness: Psychometric Properties of a New Measure." *Psychiatry Research* 121 (2003): 31-49.; Sorsdahl, Katherine R., Ritsuko Kakuma, Zane Wilson, and Dan J. Stein. "The Internalized Stigma Experienced by Members of a Mental Health Advocacy Group in South Africa." *International Journal of Social Psychiatry*, 2010: 1-6.

[91] Jussim, Lee, Polly Palumbo, Celina Chatman, Stephanie Madon, and Alison Smith. "Stigma and Self-Fulfilling Prophecies." In *The Social Psychology of Stigma*, edited by Todd F. Heatherton and et al. Guilford Press, 2000.

[92] *Id.*

[93] *Id.*

vulnerable would be imposed and supported by a publicly-funded institution meant to serve the benefit of the population. Individuals labeled as vulnerable in the research context, then, face an institutionalized reinforcement of the stigma, which may then serve to reify, justify, and allow to be perpetuated the stereotypes associated with vulnerability.

These negative implications and harms of being labeled as vulnerable stem from the conceptualization of vulnerability upon which the research protections rest, along with the framework the research regulations adopt for applying such protections. While it is important to offer protections that ensure that individuals' rights and interests are protected while participating in research, the current scheme of implementing such protections is inadequate to appropriately address the vulnerabilities of various individuals and, furthermore, causes particular harms simply by its application. In the following section, an alternative framework for assessing vulnerability is considered. However, while this alternative analytical framework avoids some of the problems of inaccurate identification of individuals to whom to apply special protections, and thus avoids some associated issues of justice, it both fails to address all forms of vulnerability which are worrisome in the research context and continues to rely on a conceptualization of vulnerability which situates it as a feature of an individual instead of within her context.

4.0 A NEW WAY OF CONCEPTUALIZING VULNERABILITY

There are compelling reasons to afford special protections to individuals in the research context, but there ought to be a way to do so which does not risk integrating the feature of vulnerability into their identity. There are moral reasons not to allow exploitative transactions, even those which may offer some benefit to the exploitee or those to which the potential exploitee gives fully voluntary, informed consent. Thus, the current framework and special protections should not be disposed of without offering an alternative way to protect vulnerable individuals. In the following sections, I will present one alternative framework that has been proposed for considering individual's vulnerability in the research context. I argue that this alternative framework, while avoiding some of the problems of inadequate sensitivity and specificity plaguing the current framework, still continues to employ the conceptualization of vulnerability which renders it to be a failing of an individual. It, in some instances, ascribes the characteristic of frailty or weakness to the individual herself, instead of focusing on the relational aspects of her circumstances or situation which render her thus susceptible to harms or wrongs. In other instances, the focus of the protection is misplaced; the protections are developed and applied to the individuals who are members of a particular subpopulation rather than applied to the particular features of their situation or circumstance which renders them vulnerable. In the final section, I will present and argue for this more relationally-focused conception of vulnerability, and discuss how it may be implemented in the research context. Although it may

be more difficult to implement, it ultimately will offer more appropriate and thorough protections to those in need, while avoiding stigmatizing and labeling individuals as unable to protect their own interests because of an individual failing.

4.1 ONE PROPOSED ALTERNATIVE FRAMEWORK FOR EMPLOYING THE CONCEPT OF VULNERABILITY

In an attempt to bring some clarity to what we are truly concerned about when we term certain groups of people as "vulnerable," Kenneth Kipnis has developed a taxonomy of vulnerabilities in which he identified the various characteristics which are the source of impaired consent. In Kipnis' schema, there are six different types of vulnerability: (1) cognitive; (2) juridic; (3) deferential; (4) medical; (5) allocational; and (6) infrastructural.[94] Through this taxonomy, Kipnis hopes to provide a framework in which to better understand what we are trying to accomplish by offering heightened protections for vulnerable individuals and groups. Using these six categories based on the nature or source of people's vulnerability, Kipnis tries to offer a scheme whereby vulnerable people are afforded better and more nuanced protections. His framework is also meant to provide protections to those who may be vulnerable but who are not included in the current categories of identified vulnerable populations. Although Kipnis's reconceptualization of vulnerability avoids some of the current problems critiqued above, it is still inadequate. First, his treatment of vulnerability in the research context focuses solely on the

[94] Kipnis, *supra* note 5, at 217.

issue of consent and the circumstances under which individual's consent may be defective. Furthermore, his schema still relies on the conceptualization of vulnerability as inherent in the individual. Although his schema focuses increased attention on the source of the vulnerability, the vulnerability itself continues to be situated within the individual or the population as a characteristic of the individual or population.

Kipnis advances a framework for instituting protections for vulnerable individuals which is not based on a "subpopulation approach,"[95] but rather on an "analytic approach" which endeavors to identify the various situations in which an individual may be rendered vulnerable and thus experience heightened susceptibility to harms or wrongs.[96] *Cognitive vulnerability* considers whether or not the potential subject has the capacity to deliberate and decide about participation in a study.[97] *Juridic vulnerability* addresses situations where an individual may be unable to give voluntary consent because of their subordinate position in a relationship of authority.[98] The concern is that the consent given represents that of the dominant member of the relationship (e.g., a parent in a parent-child relationship) and not that of the potential subject (in this example, the child). *Deferential vulnerability* may be a concern independently, or it may also occur in situations of juridic vulnerability; it represents the concern for individuals who are particularly susceptible to being harmed or wronged and are unable to give voluntary consent because they are deferential to the authority or wishes of others.[99] The *medically vulnerable* are those who have a health-related condition for which there are currently no adequate treatments and for which their consent is rendered suspect because of the duress they feel to receive any

[95] Kipnis, Kenneth. "Seven Vulnerabilities in the Pediatric Research Subject." *Theoretical Medicine* 24 (2003): 108.; He describes the current research guidelines as employing a subpopulation approach, whereby vulnerable individuals are identified as such because of their status as a member of a particular population. *Id.*
[96] *Id.*
[97] Kipnis, *supra* note 5, at 222.
[98] *Id.*, at 223.
[99] *Id.*, at 224.

possible medical treatment that will aid their recovery.[100] *Allocational vulnerability* addresses the situation of those who are lacking in some social resource that would be necessary to an ability to give voluntary informed consent.[101] Examples of these social resources would be money, medical care, or education.[102] Finally, *infrastructural vulnerability* addresses failings in the research infrastructure which would render individuals particularly open to heightened risk of being harmed or wronged.[103] For instance, if a consent form asks subjects to rely on logging questions or complaints during the course of a study via a website, this requirement assumes the availability of internet access.

The first failing of Kipnis's account of vulnerability is that it fails to consider the situation or circumstances of those who are particularly susceptible to harms or wrongs not in virtue of some failure in the decision-making context, but because of particular personal characteristics.[104] Those who are HIV-positive, for instance, would be much more gravely harmed by a breach of confidentiality than those who are HIV-negative, and thus may be appropriately described as vulnerable. Kipnis's framework, however, fails to acknowledge this sort of vulnerability.

By focusing on the source of the vulnerability or its characterization, Kipnis's schema does avoid some problems of over- and under-inclusion by defining vulnerability as based upon the particular feature or characteristic of the situation which renders one vulnerable, and thus, less often creates concerns of justice. Because under Kipnis's framework we are concerned with asking the question "*how* is an individual vulnerable," it is true that those individuals who are

---

[100] Kipnis, *supra* note 5, at 224.
[101] *Id.*, at 227.
[102] *Id.*, at 227.
[103] *Id.* at 229.
[104] "The vulnerabilities that concern us here are only those that call into question the efficacy of consent in effecting permissibility." *Id*.

relatively similarly situated in a material sense will be treated equally. Those who are vulnerable, for instance, because they experience allocational vulnerability in the form of a lack of money will be identified regardless of their membership in a particular subpopulation (e.g., poor white males will be identified as vulnerable along with poor black males), thus relevantly similarly situated individuals will be treated equally in terms of receiving protections for participating in research.

A failing of Kipnis's account of vulnerability is, however, that his framework situates the vulnerability entirely within the individual and her inability to protect her own interests; and he does not address the problems that arise from conceiving appropriate responses to vulnerability as lying within or being focused upon the individual. Although Kipnis's framework distinguishes the situational characteristics which are the cause of concern, his schema continues to conceptualize vulnerability as an individual's inability to participate in the decision-making process such that they may make a decision to participate in research by which others will abide. This approach does not remedy the aforementioned issues of stigmatization and conceptualization of those who are vulnerable as lesser individuals which result, although to the extent that vulnerability does not coincide with membership in an already stigmatized group, the negative consequences of the stigma associated with the vulnerability may be less.

Kipnis developed his analytical framework to answer the questions of what characteristics these vulnerable populations possess and how they render "those who possess them 'vulnerable.'"[105] Here, Kipnis is relying on the conceptualization of vulnerability as a feature of an individual. Although he considers one's circumstances or situation when developing his six types of vulnerability, ultimately the vulnerability is situated within the

[105] Kipnis, *supra* note 5, at 218.

individual so-characterized and their inability to protect her own interests in the face of these power inequities or deficiencies in abilities or resources. By failing to address the type of concept vulnerability is, Kipnis's framework continues to problematically situate vulnerability within individuals, and thus continues to stigmatize those deemed vulnerable

4.2 SHIFTING THE FOCUS TO VULNERABILITY'S RELATIONAL FEATURES

I suggest that vulnerability be conceptualized not as an inability to protect one's interests *per se*, but rather as the potential for an individual's assertion of her own interests to be prevented or overridden.[106] This reconceptualization does not obscure the relational aspect of vulnerability in the way that the current conceptualization does. Vulnerability is not an immutable characteristic or feature of an individual or group; rather, vulnerability exists as an expression of the characterization of the relationship between an individual and another or an individual and an institution. In the sense that is important for this work,[107] vulnerability must be considered only in relation to a particular relationship or context. No one is simply 'vulnerable' with no qualifiers or other considerations. Vulnerability, instead, ought to focus on the features of an individual's circumstance or features of the institution with which she is interacting that cause the prevalence of countervailing interests which have the potential to be more powerfully expressed and more likely respected than her own. Vulnerability ought to be conceptualized in a way that identifies the power imbalances and external features which render an individual at

[106] Or, in the case of cognitively impaired or comatose individuals, the expression of their interests by a proxy-decision-maker.

[107] That is, setting aside the sense of the term 'vulnerable' which describes all individuals as vulnerable by the mere fact of their mortality, and focusing on those cases of *particular* or *heightened* susceptibility to harms or wrongs .

particular risk of being harmed or wronged. This focus will allow for the implementation of heightened protections for those who would truly benefit from them, while avoiding the ascription of vulnerability as a failure or defective characteristic which is a necessary feature of an individual. The relational features are moved to the forefront and become more easily expressed and viewed as changeable and context-dependent, and as functions of a relationship rather than features of an individual herself. We can then address the differences among individuals while avoiding the stigmatization and hindrance that a label may and currently does cause.

This new conceptualization would continue to recognize those who are 'traditionally' considered vulnerable, those individuals who are members of the vulnerable populations currently recognized by the research guidelines and who are particularly susceptible because of a lack of capacity, a likelihood of experiencing undue pressure, or a potential to be harmed or wronged more severely or more frequently. Institutionalized elderly individuals, for instance, are sometimes (but only sometimes) vulnerable in the context of research participation under this new conceptualization because it may be that their interests are easily overridden by those of the researchers (if the researchers are affiliated with the institution where the elderly individual lives) who have greater power and influence to ensure that their interests are expressed over those of the institutionalized elderly individual.

Framing the vulnerability in the context of the circumstances or other actors who may have greater power and override an expression of an individual's own interest also allows for protections to be crafted which do not focus solely on the individual. Taking the previous example, an institutionalized elderly individual is not per se unable to express or protect her own interests. It is only when that expression of her interests is likely to be disregarded or overridden

by other actors that the vulnerability is 'created.' Thus, vulnerability no longer becomes a descriptive feature or fact of being an institutionalized elderly individual. The vulnerability becomes a description of the context in which these individuals may find themselves in regard to making a particular decision (here, the decision to participate in research). Special protections, then, can be developed in light of this characterization of vulnerability, may better serve the elderly individuals interests, and may allow for the crafting of more appropriate solutions which better protect individuals in the various situations and contexts in which they may face becoming vulnerable. The protections would less likely rely on measures which may ultimately result in the exclusion of the institutionalized elderly individual from research, and more focus could be drawn to features of her situation (e.g., measures within the institution itself, measures that affect the investigator) which could be modified to allow for her participation and the protection of an expression of her interests.

Conceptualizing the institutionalized elderly individual's vulnerability as a feature of her being asked to make this particular decision in this particular context better suggests that an appropriate protection or safeguard be directed towards the situation in which she finds herself, not applied to the individual herself. Instead of offering protections in a form which impacts the individual's ability to make a decision about whether or not to participate in research, the solution or safeguard can be directed toward features of her situation which would cause her interests to be ignored or overridden. Suggested protections, based on this conceptualization, may be focused on the actors within the research context, as well as structural or background conditions, and not on the opportunity for the individual to participate in research.

Although this is only one brief example, it nicely illustrates how a reconceptualization of vulnerability will allow for needed protections to be offered in the context of research

participation, while avoiding harming those who are in need of such protections. Expressions of individual's interests can be safeguarded, and individuals can be better protected against experiencing more severe or more frequent harms or wrongs, when the protections are based on a theory of vulnerability which does not obscure the relational or contextual features which are necessary to properly consider how particular individuals are vulnerable.

This reconceptualization would serve to address each of the critiques levied in sections two and three, while still allowing for the addition of protections for individuals who would benefit from them and whose interests may otherwise be overridden. First, the reconceptualization of vulnerability would require that the identification of those who would benefit from special protections be based not upon membership in a class defined by social status or biological features necessarily, but rather upon the identification of the relevant contextual or societal features of each individual's particular situation. Secondly, the presence of the worrisome circumstances in any individual's case ought to serve as a trigger for making a deeper inquiry about the likelihood of an expression of that individual's interests to be overridden, not as grounds for her exclusion from attempting to express those interests. Furthermore, the trigger ought to begin an inquiry into the types of protections that can be enacted which would address features of that individual's situation, and not serve as a basis for protections which almost inevitably lead to her exclusion from research. Finally, an approach to offering protections based upon this reconceptualization of vulnerability as relational, contingent, and context dependent will better address the problems associated with essentialization and reification of those negative characteristics associated with being vulnerable, which in turn can serve to justify and uphold the stigma-based stereotypes, which may be internalized. All three of these features are an integral

part of a reconceptualization of vulnerability that makes progress toward adequately addressing the practical and conceptual problems raised in critique of the current framework.

5.0 CONCLUSION

Vulnerability is conceptualized as the inability of an individual to protect her own interests and recognizes those who may be particularly susceptible to being harmed, wronged, or exploited. In the research context, special protections are developed and extended to individuals who are members of particular populations which have been deemed to be vulnerable as a result of a lack of decision-making capacity, a particular susceptibility to undue pressures which would render their decisions involuntary, a proneness to suffering harms or wrongs to a greater frequency or of a greater severity, or a combination of these susceptibilities. Although it is important to endeavor to avoid harming, wronging, or exploiting individuals in the research enterprise, the current vulnerability framework is inadequate in a number of ways.

The label is not sensitive enough to adequately identify and treat equally all of those who are vulnerable in a particular way, which in some cases causes inadequate protection of those who would benefit from being protected. It is also insufficiently specific and may impose special protections on those who do not need them or totally exclude them from research participation. Furthermore, it also inappropriately suggests that the vulnerability is an integral "fact" or feature of the individual, which may lead to stigma and a general view of vulnerable individuals are somehow less worthy as individuals, a stigma which may then be internalized by the individuals so-labeled.

Although it is appropriate to offer protections which seek to ensure that the interests of individuals are adequately safeguarded and that they are not unduly harmed, wronged, or exploited by participation in research, the way that these protections are currently offered, and the way that vulnerability is used to signify a need for protections, is inadequate. The offer of heightened protections in human subject research ought to be based on a different conceptualization of vulnerability. Vulnerability ought to be conceptualized in a way that focuses on how it results from various relationships and contexts. Individuals are not generally wholly vulnerable; instead, they are vulnerable in particular contexts, with respect to the particular decision they are making or the individual or institution with whom or with which they are interacting. Starting from this conceptualization of vulnerability, research protections can be developed which would avoid the particular issues of justice, ascription of weakness, and stigmatization which are discussed above. It is only in light of this reconceptualization of vulnerability that individuals can be treated differently while avoiding hindering or harming them on that very basis.

BIBLIOGRAPHY

Amdur, Robert J., and Elizabeth A. Bankert, *Institutional Review Board Member Handbook*. Jones & Bartlett Publishers, Inc. 2007.

Appiah, Kwame Anthony. *The Ethics of Identity.* Princeton: Princeton University Press, 2005.

Ballantyne, Angela, and Wendy Rogers. "Vulnerability and Protection in Human Research." *Harvard Health Policy Review* 8 (2007): 29-42.

Balshem, Martha. "Cancer, Control, and Causality: Talking about Cancer in a Working-Class Community." *American Ethnologist* 18 (1991): 152-172.

Beauchamp, Tom L., and James F. Childress. *Principles of Biomedical Ethics.* 6th ed. New York: Oxford University Press, 2009.

Berg, Jessica W., Paul S. Appelbaum, Lisa S. Parker, and Charles W. Lidz. *Informed Consent: Legal Theory and Clinical Practice.* 2nd ed. New York: Oxford University Press, 2001.

Blacksher, Erika. "On Being Poor and Feeling Poor: Low Socioeconomic Status and the Moral Self." *Theoretical Medicine* 23 (2002): 455-470.

Blacksher, Erika, and John R. Stone. "Introduction to "Vulnerability" Issues of Theoretical Medicine and Bioethics." *Theoretical Medicine* 23 (2002): 421-424.

Brennan, William. *Dehumanizing the Vulnerable: When Word Games Take Lives.* Life Cycle Books, Ltd., 1995.

Buchanan, Allen E., and Dan W. Brock. *Deciding for Others: The Ethics of Surrogate Decision Making.* New York: Cambridge University Press, 1990.

Bury, Michael, and Jonathan Gabe, . *The Sociology of Health and Illness: A Reader.* New York: Routledge, 2004.

Bustillos. "Limited English Proficiency and Disparities in Clinical Research." *Journal of Law, Medicine and Ethics* 37, no. 1 (2009): 28-37.

Butler, Judith. *Excitable Speech: A Politics of the Performative.* New York: Routledge, 1997.

Campbell, Amy T. ""Vulnerability" in Context: Recognizing the Sociopolitical Influences." *American Journal of Bioethics* 4, no. 3 (2004): 58-59.

Coleman, Carl H. "Vulnerability as a Regulatory Category in Human Subject Research." *Journal of Law, Medicine and Ethics* 37, no. 1 (2009): 12-18.

Council for International Organizations of Medical Sciences (CIOMS). "International Ethical Guidelines for Biomedical Research Involving Human Subjects." 2002, available at http://www.cioms.ch/publications/layout_guide2002.pdf (last visited April 1, 2011).

DeBruin, Debra A. "Looking Beyond the Limitations of "Vulnerability": Reforming Safeguards in Research." *American Journal of Bioethics* 4, no. 3 (2004): 76-78.

Dodds, Susan. "Choice and Control in Feminist Bioethics." In *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self*, edited by Catriona Mackenzie and Natalie Stoljar. Oxford University Press, 2000.

Dolon, Rosana, and Julia Todoli, . *Analysing Identities in Discourse.* Philadelphia: John Benjamins, 2008.

Dresser, Rebecca. "First-in-Human Trial Participants: Not a Vulnerable Population, but Vulnerable Nonetheless." *Journal of Law, Medicine and Ethics* 37, no. 1 (2009): 38-50.

Emanuel, Ezekiel, David Wendler, and Christine Grady. "What Makes Clinical Research Ethical?" *Journal of the American Medical Association* 283 (2000): 2701-2711.

Emanuel, Ezekiel, et al., “Oversight of Human Participants Research: Identifying Problems to Evaluate Reform Proposals” *Annals of Internal Medicine* 141 (2004): 282-291.

Faden, Ruth R., and Tom L. Beauchamp. *A History and Theory of Informed Consent.* Oxford University Press, 1986.

Feder Kittay, Eva, and Ellen K. Feder, . *The Subject of Care: Feminist Perspectives on Dependency.* Rowan & Littlefield Publishers, Inc., 2002.

Feinberg, Joel. "Harm and Offense." In *Encyclopedia of Ethics*, edited by Lawrence C. Becker and Charlotte B. Becker. New York: Routledge, 2001.

Finder, Stuart G. "Vulnerability in Human Subject Research: Existential State, not Category Designation." *American Journal of Bioethics* 4, no. 3 (2004): 68-70.

Ford, Paul J. "Vulnerable Brains: Research Ethics and Neurosurgical Patients." *Journal of Law, Medicine, and Ethics* 37, no. 1 (2009): 73-82.

Fox, Ken. "Hotep's Story: Exploring the Wounds of Health Vulnerability in the US." *Theoretical*

Medicine 23, no. 6 (2002): 471-497.

Garcia, Sandra Anderson. "Equal Protection Clause Enforcement as a Model for Protecting Vulnerable Human Research Subjects." *American Journal of Bioethics* 4, no. 3 (2004): 81-82.

Goffman, Erving. *Stigma: Notes on the Management of Spoiled Identity*. Simon & Schuster, Inc., 1963.

Grady, Christine. "Vulnerability in Research: Individuals with Limited Financial or Social Resources." *Journal of Law, Medicine and Ethics* 37, no. 1 (2009): 19-27.

Heimer, Carol A., and JuLeigh Petty. "Bureaucratic Ethics: IRBs and the Legal Regulation of Human Subjects Research." *Annual Review of Law and Social Science* 6 (2010): 601-626.

Henderson, Gail E., Arlene M. Davis, and Nancy M.P. King. "Vulnerability to Influence: A Two-Way Street." *American Journal of Bioethics* 4, no. 3 (2004): 50-51.

Hill, John Lawrence. "Exploitation." *Cornell Law Review* 79 (1994): 631-699.

Iltis, Ana S. "Introduction: Vulnerability in Biomedical Research." *Journal of Law, Medicine, and Ethics* 37 (2009): 6-11.

Jaggar, Alison M. "Vulnerable Women and New-Liberal Globalization: Debt Burdens Undermine Women's Helath in the Global South." *Theoretical Medicine* 23 (2002): 425-440.

Jecker, Nancy S. "Protecting the Vulnerable." *American Journal of Bioethics* 4, no. 3 (2004): 60-62.

Jotkowitz, Alan B. "Vulnerability from a Global Medicine Perspective." *American Journal of Bioethics* 4, no. 3 (2004): 62-63.

Jussim, Lee, Polly Palumbo, Celina Chatman, Stephanie Madon, and Alison Smith. "Stigma and Self-Fulfilling Prophecies." In *The Social Psychology of Stigma*, edited by Todd F. Heatherton and et al. Guilford Press, 2000.

Justo, Luis. "Participatory Research: A Way to Reduce Vulnerability." *American Journal of Bioethics* 4, no. 3 (2004): 67-68.

Kipnis, Kenneth. "Seven Vulnerabilities in the Pediatric Research Subject." *Theoretical Medicine* 24 (2003): 107-120.

Kipnis, Kenneth. "The Limitations of "Limitations"." *American Journal of Bioethics* 4, no. 3 (2004): 70-72.

Kipnis, Kenneth. "Vulnerability in Research Subjects: An Analytical Approach." In *The Variables of Moral Capacity*, edited by David C. Thomasma and David N. Weisstub, 217-231. Kluwer Academic Publishers, 2004.

Kopelman, Loretta M. "Adolescents as Doubly-Vulnerable Research Subjects." *American Journal of Bioethics* 4, no. 1 (2004): 50-54.

Kottow, Michael H. "The Vulnerable and the Susceptible." *Bioethics* 17 (2003): 460-471.

Kottow, Michael H. "Vulnerability: What Kind of Principle Is It?" *Medicine, Health Care, and Philosophy* 7 (2004): 281-287.

Levine, Carol. "Research Involving Economically Disadvantaged Participants." In *The Oxford Textbook of Clinical Research Ethics*, edited by Ezekiel J. Emanuel, Christine Grady, Robert A. Crouch, Reidar K. Lie, Franklin G. Miller and David Wendler, 431-436. New York: Oxford University Press, 2008.

Levine, Carol, et al. "The Limitations of "Vulnerability" as a Protection for Human Research Participants." *American Journal of Bioethics* 4, no. 3 (2004): 44-49.

Luna, Florencia. "Elucidating the Concept of Vulnerability: Layers Not Labels." *International Journal of Feminist Approaches to Bioethics* 2 (2009): 121-139.

Macklin, Ruth. "Bioethics, Vulnerability, and Protection." *Bioethics* 17 (2003): 472-486.

Marco, Joseph P. "Vulnerability: A Needed Moral Safeguard." *American Journal of Bioethics* 4, no. 3 (2004): 82-84.

Maschke, Karen J. "Human Research Protections: Time for Regulatory Reform?" *Hastings Center Report* 38, no. 2 (2008): 19-22.

Menikoff, Jerry. "The Vulnerability of the Very Sick." *Journal of Law, Medicine and Ethics* 37, no. 1 (2009): 51-58.

Merton, Robert K. "The Self-Fulfilling Prophecy." *The Antioch Review* 8, no. 2 (1948): 193-210.

Minow, Martha. *Making All the Difference: Inclusion, Exclusion and American Law.* Cornell University Press, 1991.

Moreno, Jonathan D. "The Natural History of Vulnerability." *American Journal of Bioethics* 4, no. 3 (2004): 52-53.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral

Research. "Ethical Principles and Guidelines for the Protection of Human Subjects of Research ("The Belmont Report")." 1979, available at http://ohsr.od.nih.gov/guidelines/belmont.html (last visited April 1, 2011).

"National Research Act of 1974." Public Law 93-348.

Nickel, Philip J. "Vulnerable Populations in Research: The Case of the Seriously Ill." *Theoretical Medicine* 27, no. 3 (2006): 245-264.

Noddings, Nel. "Caring, Social Policy, and Homelessness." *Theoretical Medicine* 23, no. 6 (2002): 441-454.

Office for Protection from Research Risks (OPRR). "Institutional Review Board Guidebook." 1993, available at http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm (last visited April 1, 2011).

O'Neill, Onora. *Towards Justice and Virtue: A Constructive Account of Practical Reasoning.* 2nd prtg. Cambridge University Press, 1998.

Pasquerella, Lynn. "Confining Choices: Should Inmates' Participation in Research be Limited?" *Theoretical Medicine* 23 (2002): 519-536.

Prograis Jr., Lawrence, and Edmund D. Pellegrino, . *African American Bioethics: Culture, Race, and Identity.* Georgetown University Press, 2007.

"Protection of Human Subjects." 2005, 45 C.F.R. §46.

Resnik, David B. "Exploitation in Biomedical Research." *Theoretical Medicine* 24, no. 3 (2003): 233-259.

Resnik, David B. "Research Subjects in Developing Nations and Vulnerability." *American Journal of Bioethics* 4, no. 3 (2004): 63-64.

Ritsher, Jennifer Boyd, Poorni G. Otilingam, and Monica Grajales. "Internalized Stigma of Mental Illness: Psychometric Properties of a New Measure." *Psychiatry Research* 121 (2003): 31-49.

Satz, Ani B. "Disability, Vulnerability, and the Limites of Antidiscrimination." *Washington Law Review* 83 (2008): 513-568.

Sayles, Jennifer N., and et al. "Development and Psychometric Assessment of a Multidimensional Measure of Internalized HIV Stigma in a Sample of HIV-Positive Adults." *AIDS Behavior* 12, no. 5 (2008): 748-758.

Schoene-Seifert, Bettina. "Harm." In *Encyclopedia of Bioethics*, edited by Stephen Garrad Post, 1033. MacMillan Reference Library, 2003.

Shapiro, Johanna, and et al. "Literary Narratives Examining Control, Loss of Control and Illness: Perspectives of Patient, Family, and Physician." *Families, Systems and Health* 18 (2000): 441-454.

Shivas, Tricia. "Contextualizing the Vulnerability Standard." *American Journal of Bioethics* 4, no. 3 (2004): 84-86.

Silvers, Anita. "Historical Vulnerability and Special Scrutiny: Precautions Against Discrimnation in Medical Research." *American Journal of Bioethics* 4, no. 3 (2004): 56-57.

Singh, Ishtla, and Jean Stilwell Peccei, . *Language, Society and Power: An Introduction.* 2nd ed. New York: Routledge, 2004.

Solyom, Antal E. "Ommitted Considerations and Populations: A Response to "Should Children Decide Whether They are Enrolled in Nonbeneficial Research?" by David Wendler and Seema Shah (AJOB 3:4)." *American Journal of Bioethics* 4, no. 1 (2004): W39-W40.

Sorsdahl, Katherine R., Ritsuko Kakuma, Zane Wilson, and Dan J. Stein. "The Internalized Stigma Experienced by Members of a Mental Health Advocacy Group in South Africa." *International Journal of Social Psychiatry*, 2010: 1-6.

Stone, John. "Race and Healthcare Disparities: Overcoming Vulnerability." *Theoretical Medicine* 23 (2002): 499-518.

Tait, Raymond C. "Vulnerability in Clinical Research with Patients in Pain: A Risk Analysis." *Journal of Law, Medicine and Ethics* 37, no. 1 (2009): 59-72.

"The Declaration of Helsinki." 1964, available at http://www.wma.net/en/30publications/10policies/b3/17c.htm (last visited April 1, 2011).

Thomasma, David. "The Vulnerability of the Sick." *Bioethics Forum* 16, no. 2 (2000): 5-15.

Tronto, Joan. *Moral Boundaries: A Political Argument for an Ethic of Care.* Taylor & Francis, Inc., 1993.

"U.S. v. Karl Brandt, et al." 1947.

Vander Walde, Ari M. "Vulnerability as the Inability of Researchers to Act in the Best Interest of a Subject." *American Journal of Bioethics* 4, no. 3 (2004): 65-66.

Wendell, Susan. *The Rejected Body: Feminist Philosophical Reflections on Disability.* New York: Routledge, 1996.

Wertheimer, Alan. *Exploitation.* New Jersey: Princeton University Press, 1996.

Wilkerson, Abby L. *Diagnosis: Difference: The Moral Authority of Medicine.* Ithaca: Cornell University Press, 1998.

World Health Organization, Health Dimensions of Economic Reform (1992) available at http://whqlibdoc.who.int/hq/1991/57259_(part1).pdf (last visited April 18, 2011).

Young, Iris Marion. "Breasted Experience: The Look and the Feeling." In *On Female Body Experience: "Throwing Like a Girl" and Other Essays*, by Iris Marion Young, 75-96. New York: Oxford University Press, 2005.

—. *Justice and the Politics of Difference.* Princeton: Princeton University Press, 1990.